

U.S. Serial No. 08/803,702

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 21 2006

In Re: Patent Application

Applicant(s): Maino et al. Docket No.: P-3639P1
Serial No.: 08/803,702 Group Art Unit: 1644
Filing Date: February 21, 1997 Examiner: Gerald Ewoldt, Ph.D.
For: METHOD FOR DETECTING T CELL RESPONSE
TO SPECIFIC ANTIGENS IN WHOLE BLOOD

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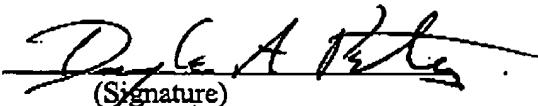
- PETITION UNDER 37 C.F.R. §1.181 (8 pages)

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Sir:

In the Notification of Non-Compliant Appeal Brief (37 CFR 41.37) mailed May 22, 2006, the examiner held that the Appeal Brief filed January 24, 2005, in the above-referenced case is defective for failure to comply with 37 CFR 41.37. Appellants assert that the holding of noncompliance is improper and without merit. Appellants petition to withdraw the holding of noncompliance for the reasons set forth herein.

The examiner's reasons for the holding of noncompliance

In the Notification of Non-Compliant Appeal Brief (37 CFR 41.37), (PTOL-462), Examiner held that the Appeal Brief filed January 24, 2005, in the above-referenced case is defective for failure to comply with 37 CFR 41.37 (c)(1)(v) (PTOL-462 box 4). In the Continuation Sheet (PTOL-462), the examiner provided an explanation and/or additional reasons.

The explanation provided in the Continuation Sheet set forth four reasons for the holding of noncompliance, which are listed below. To facilitate review, following each restated reason, the corresponding text from the Continuation Sheet is quoted.

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I. The summary cannot be considered to be concise.

This reason was stated in the Continuation Sheet at lines 3-4 as follows:

First note that the 6 page Summary cannot be considered to be "concise" as the majority of it comprises background.

II. The page and line number cites do not disclose the steps of the claimed method for which they are cited.

This reason was stated in the Continuation Sheet at lines 4-8:

Further note that many of the page and line number cites do not disclose the steps of the claimed method for which they are cited. For example, page 5, lines 15-17 are cited as disclosing the second step of Claim 19. Yet a review of the lines discloses that they merely indicate the concept that the use of agents that block intracellular cytokine secretion enhances their detection when added for a 4 hour incubation. This concept that applies only to a specific time frame, does not describe or support the step of the claimed method for which it is cited.

III. Claim 39 is not separately summarized.

This reason was stated in the Continuation Sheet at lines 8-9 as follows:

Further, it is noted that at page 31 Appellant states that Claim 39, which was not separately summarized as would be required,

IV. The listing of the groupings of claims that stand and fall together is not consistent.

This reason was stated in the Continuation Sheet at lines 8-11 as follows:

Further, it is noted that at page 31 Appellant states that Claim 39 [...], stands only with Claim 64 in respect to enablement. Regarding the claims standing of falling together for lack of enablement, at page 25 Appellant states that all the claims on appeal stand or fall together, yet at page 31 Appellant states that Claims 39 stand only with Claim 64 and at page 32 Appellant states that Claim 65 stands alone.

Points to be Reviewed

Appellants request review of each of the reasons for the holding of non-compliance.

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The Examiner's holding of noncompliance is in error and should be withdrawn

Appellants assert that the holding of noncompliance is in error and should be withdrawn for the reasons set forth, below.

I. The examiner's allegation that the summary cannot be considered to be "concise" is in error.

The Appeal Brief contains a concise explanation of the independent claims starting near the bottom of page 10, "Subject Matter of the Independent Claims", through page 12 (i.e., approximately two full pages of text). Because of the highly technical subject matter of the claims, Appellants additionally provided a separate background section to aid in understanding the claimed invention. The Appeal Brief clearly identifies the background section as separate from the concise explanation of the independent claims:

To aid in understanding the claimed invention, Appellants' first provide, as background, a summary of terms and concepts from the field of immunology relevant to the claimed invention. Appellants then provide a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which are claims 19, 64, and 65.

Appeal Brief, page 7, first paragraph (emphasis added). The background section follows immediately at page 7 under the header "Background", and the concise explanation of the independent claims follows the background section at page 10 under the header "Subject Matter of the Independent Claims".

37 CFR 41.37 requires a concise explanation of the subject matter defined in each of the independent claims. However, 37 CFR 41.37 does not preclude including an additional background section to facilitate understanding the claimed invention. The examiner erred by improperly treating these two separate sections as one.

For the above reasons, the examiner's allegation that the summary cannot be considered to be "concise" is in error. The Appeal Brief does include a concise explanation of the subject matter defined in each of the independent claims involved in the appeal and, thus, satisfies this requirement of 37 CFR 41.37 (c)(1)(v).

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II. The examiner's allegation that the page and line number cites do not disclose the steps of the claimed method for which they are cited is in error.

Although the examiner suggested that "many of the page and line number cites do not disclose the steps of the claimed method for which they are cited" (see Continuation Sheet, *supra*), the examiner provided only a single example. A vague statement suggesting the existence of "many" informalities is improper. Appellants address the sole example, the citation of page 5, lines 15-17, as disclosing the second step of claim 19, below.

The Appeal Brief provides a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which refers to the specification by page and line number, at pages 10-12. Within this concise explanation, at page 11, the Appeal Brief cites page 5, lines 15-17, of the specification as describing step 2 of claim 19, which is the step of "adding to said sample an inhibitor of cytokine secretion". The cited passage of the specification (page 5, lines 15-17) reads:

Further, it has been found that intracellular cytokine detection is enhanced when an agent which blocks the secretion of such intracellular cytokines is added during the activation

(4h) period of incubation. A preferred agent is Brefeldin A.

The examiner suggested that that the cited passage does not describe or support step 2 of claim 19 because the description is limited to a specific activation time and, thus, the Appeal Brief fails to provide a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which refers to the specification by page and line number. Appellants assert that the examiner's statement is improper for several reasons, set forth below.

First, the examiner essentially introduced a new ground of rejection under either the written description requirement or enablement requirement of 35 USC §112, or both, improperly stated as a formal non-compliance of the Appeal Brief. The examiner's suggestion that the citation in the specification applies only to a specific activation time and, thus, does not describe or support the claimed method was not raised during prosecution and represents a new ground of rejection. This attempt to introduce a new ground of rejection disguised as formal noncompliance of the Appeal Brief is improper.

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Furthermore, an appeal of an adverse decision by an examiner properly should be heard by the Board. In the present case, both a rejection for lack of written description and a rejection for lack of an enabling disclosure are under appeal. The examiner improperly attempts to adjudicate these issues as a formal matter, rather than to allow the appeal to be heard by the Board. It is improper to restate a rejection for lack of written description (or enablement) in the specification as a holding that an appeal brief is noncompliant for lack of written description (or enablement) in those sections of the specification cited in the concise explanation of the claimed subject matter. Appellants point out that, if the examiner's position were allowed to stand, it essentially would render impossible any appeal of an adverse decision on written description or enablement because it would render impossible the preparation of a compliant Appeal Brief.

Furthermore, the examiner applied an improper standard for judging the formal adequacy of the Appeal Brief. 37 CFR 41.37 (c)(1)(v) requires a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which refers to the specification by page and line number. "The purpose of the requirement is to aid the Board in considering the subject matter of the independent claims so that an informed review of the examiner's adverse determination of patentability can be made."¹ Meeting the requirement for including citations in the concise explanation, meant to aid the Board, does not require Appellants to forfeit the right to have the specification as a whole considered under the requirements of 35 U.S.C. §112. The examiner, by separately reviewing the cited portions of the specification for compliance with the written description and enablement requirements of 35 U.S.C. §112, applied a improper standard for judging the formal adequacy of the Appeal Brief that is in conflict with 35 U.S.C. §112.

For each of the above reasons, allegation that the page and line number cites do not disclose the steps of the claimed method for which they are cited is in error. The Appeal Brief does provide a concise explanation of the subject matter defined in each of the

¹ Quoted from "Rules of Practice Before the Board of Patent Appeals and Interferences" Federal Register, Vol. 69, No. 155, page 49976, answer to comment 53 regarding the standard of 37 CFR 41.37(c)(1)(v))

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independent claims involved in the appeal, which refers to the specification by page and line number and, thus, satisfies this requirement of 37 CFR 41.37 (c)(1)(v).

III. The examiner's statement that Claim 39 must be separately summarized is in error.

The first sentence of 37 CFR 41.37 (c)(1)(v) "*Summary of claimed subject matter*" sets forth that the Appeal Brief shall contain:

A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number,
and to the drawing, if any, by reference characters.

37 CFR 41.37 (c)(1)(v) (emphasis added). None of the claims involved in the appeal contain means plus function or step plus function language as permitted by 35 U.S.C. 112, sixth paragraph, and thus, the second sentence² of 37 CFR 41.37 (c)(1)(v) is not applicable.

The Appeal Brief provides a concise explanation of the subject matter defined in claims 19, 64, and 65 at pages 10-12. Claims 19, 64, and 65 are the only independent that are involved in the appeal (independent claim 66 is allowed and not under appeal). Claim 39 is a dependent claim that depends from claim 19. Thus, the Appeal Brief summarizes the subject matter defined in each of the independent claims involved in the appeal and satisfies this requirement of 37 CFR 41.37 (c)(1)(v).

Appellants point out that the examiner clearly applied an incorrect requirement. The examiner erroneously stated that "37 CFR 41.37 requires a concise explanation of the subject matter defined in each of the independent claims as well as for each dependent claim argued separately, referring to the specification by page and line number" (see Continuation Sheet, *supra*, emphasis added), which clearly is in conflict with the wording of 37 CFR 41.37 (c)(1)(v).

² The second sentence of 37 CFR 41.37 (c)(1)(v) sets forth that the Appeal Brief shall contain: "For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters."

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For the above reasons, the examiner's statement that Claim 39 must be separately summarized is in error. The Appeal Brief does provide a concise explanation of the subject matter defined in each of the independent claims involved in the appeal and, thus, complies with this requirement of 37 CFR 41.37 (c)(1)(v).

IV. The examiner's allegation that the listing of the subsets of claims that stand and fall together is not consistent is in error.

Appellants point out that the examiner's allegation that the listing of the subsets of claims that stand and fall together is not consistent is based on a misreading of the Appeal Brief. This is apparent from an inspection of the text of the Appeal Brief.

The claims rejected under the second ground (the enablement requirement of 35 U.S.C. §112, first paragraph), which are listed in the Appeal Brief at pages 13 and 21, are claims 19-24, 26-33, 35-55, and 61-65. Appellants separately argue three groups of claims.

The first grouping of claims is identified in the Appeal Brief at page 25 ("Claims 19-24, 26-33, 35-38, 40-55, and 61-63 stand or fall together with respect to the present rejection."). The second claim grouping, which consists of claims 39 and 64, is identified in the Appeal Brief at page 31. The third claim grouping, which consists of claim 65, is identified in the Appeal Brief at page 35. These three grouping divide the set of claims subject to the enablement rejection into three disjoint sets.

Appellants point out that, contrary to the examiner's assertion, the Appeal Brief does not state at page 25 that all the claims on appeal stand or fall together - the first grouping, listed at page 25, does not include claims 39, 64, and 65, which part of groupings 2 or 3.

For the above reasons, the examiner's allegation that the listing of the subsets of claims that stand and fall together is not consistent is in error. The Appeal Brief properly defines the groups of claims that stand or fall together and provides separate argument for each. Thus, the Appeal Brief complies with this requirement of 37 CFR 41.37.

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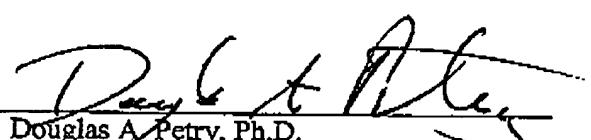
Action Requested

For the reasons set forth above, Appellants maintain that the examiner's holding of noncompliance is in error and should be withdrawn. Appellants request withdrawal the holding of noncompliance under 37 CFR 41.37.

Respectfully submitted,

6/21/06

Date



Douglas A. Petry, Ph.D.

Reg. No. 35,321

Agent for Applicants

Becton Dickinson and Company

1 Becton Drive

Franklin Lakes, NJ, 07417

Tel: (408) 518-5074

Fax: (408) 432-6493